

## FDA: Reporting Device-Related Adverse Events

By Susan Walker, Department of Health/LQA

An important part of the Food and Drug Administration (FDA) program for regulating medical devices is surveillance of problems with FDA-approved devices after they enter the marketplace. The FDA surveillance process ensures safety and timely identification of problems.

When the FDA identifies problems, it works with manufacturers to take necessary action to protect the public's health. Examples of FDA actions include educational tools such as publications, public health notices, workshops, joint communications with CDC -- MMWR reports, and enforcement tools such as recalls, directed inspections, and labeling changes.

Required reporting of adverse events that result in serious patient injury or death: The FDA requires manufacturers, importers, and health care professionals in hospitals and outpatient diagnostic facilities to report adverse events as follows:

- **Death:** File the report with both the FDA and the device manufacturer.
- **Serious patient injury:** File the report with the manufacturer only, unless the manufacturer is unknown. If the manufacturer is unknown, file it with the FDA.
- **File [FDA Form 3500A](#)** or an electronic equivalent no later than 10 working days from the time personnel become aware of the event.

\*Note: The Washington State Department of Health

requires certain facilities to report certain adverse events to its [Adverse Events Reporting](#) program, including those related to devices.

The FDA defines serious patient injury as one that:

- is life-threatening;
- or results in permanent impairment of a body function or permanent damage to a body structure;
- or necessitates medical or surgical intervention to preclude permanent impairment of a body function, or permanent damage to a body structure.

Note: Inaccurate test results produced by an in-vitro diagnostic device (IVD) and reported to the health care professional may lead to medical situations that fall under the definition of serious injury. These are reportable adverse events.

**Voluntary reporting of other adverse events:** The FDA

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### Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the [LQA website](#).

Acute Diarrhea	Lipid Screening
Anemia	PAP Smear Referral
ANA	Point-of-Care Testing
Bioterrorism Event Mgmt	PSA
Bleeding Disorders	Rash Illness
Chlamydia	Red Cell Transfusion
Diabetes	Renal Disease
Group A Strep Pharyngitis	STD
Group B Streptococcus	Thyroid
Hepatitis	Tuberculosis
HIV	Urinalysis
Infectious Diarrhea	Wellness
Intestinal Parasites	

# Washington's Laboratory Complaint Process

The Laboratory Quality Assurance (LQA) office investigates all relevant complaints concerning laboratories licensed under the medical test site (MTS) law. The office doesn't investigate complaints about OSHA/WISHA concerns, or billing issues. LQA requests that complaints be made in writing outlining the specific details of the issue that laboratory administration cannot or has not been able to resolve. The identity of the complainant is not required; however, if the investigation results in legal action, LQA cannot guarantee the anonymity of the complainant in those proceedings. Washington State has a whistleblower law to protect employees who file complaints against their employer.

Use these contact options to file a complaint about a laboratory, hospital, pharmacy, other licensed facility, and licensed professionals. LQA itself does not investigate complaints about physicians, nurses, or any other health care professionals, but the complaint can be filed using the same contact information below.

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NOTE: Letters to the editor may be published unless specified otherwise by the author.

**Website access:**

[Department of Health](#)  
[Laboratory Quality Assurance](#)  
[Public Health Laboratories](#)

Online (new): [Complaint Form](#)

Email: [HSQAComplaintIntake@doh.wa.gov](mailto:HSQAComplaintIntake@doh.wa.gov)

Mail: Washington State Department of Health  
Health Systems Quality Assurance  
Complaint Intake  
P.O. Box 47857  
Olympia, WA 98504-7857

Fax: 360-236-2626

Note: There is a link to the Complaint Process on the LQA website. From our main page,:

- Choose "[File a Complaint](#)"
- Select the link "[Health Facility Complaint Information](#)":
- Review the FAQ and select "How do I file a complaint"
- Be sure to leave your name and daytime phone number with area code.

You may also file a complaint by printing and completing the [Complaint Form](#)

Mail the completed form to:

Department of Health  
P.O. Box 47857  
Olympia, WA 98504-7857

Every complaint is evaluated and prioritized by its potential effect on consumers, residents, or patient health and safety. Based on the priority of the complaint, we conduct an investigation that may include an on-site unscheduled visit, interviews, and records review. When the investigation is complete, a letter is sent to the person who filed the complaint. State regulations do not allow the release of the investigation findings until the investigation is complete.

# FDA Reporting Adverse Events (cont'd from page 1)

requires manufacturers to report when a device fails to perform as intended and there is a chance of death or serious injury because there may be a recurrence of the malfunction. The FDA encourages health care professionals in hospitals and outpatient diagnostic facilities to:

- report device malfunctions to manufacturers. Malfunctions may relate to any aspect of a test including hardware, labeling, reagents, calibration, or user error that may be related to faulty instrument instructions or design.
- submit voluntary reports of device malfunctions and patient injuries that do not qualify as serious injuries by using [FDA Form 3500A](#).
- submit voluntary reports of adverse events noted in the course of clinical care, not events that occur in the course of clinical trial or other studies. Instructions on how to submit a voluntary report are on the [FDA website](#).

**Laboratory policies:** The clinical laboratory should have written procedures for

- identifying and evaluating adverse patient events,
- the timely submission of required medical device reports, and
- compliance with record-keeping requirements.

**Laboratories that are part of a larger organization (e.g., hospital laboratories) should:**

- document participation in the overall institutional medical device reporting (MDR) process.
- educate personnel in the FDA MDR requirements.
- submit an annual report of device-related deaths and serious injuries to FDA if any such event was reported during the previous year. Annual reports must be submitted on [FDA Form 3419](#) or an electronic equivalent by January 1 of each year. The laboratory or institution must keep records of MDR reports for two years.

## MTS Records Needed For Your Inspection

by Susan Walker, Department of Health/LQA

When preparing for your medical test site initial or regular inspection, you should remember that any documentation from the past two years is subject to review. The laboratory surveyor will typically ask to see the laboratory and testing area. Then, the surveyor will ask if any new tests or personnel were added in the past two years. New tests should not be an issue because the laboratory is required to submit to the Department of Health-Laboratory Quality Assurance Program a “Change of Test Menu” form whenever tests are added or deleted. The following general documents should be available for review by the surveyor:

**Technical Procedures:**

- Quality control policies
- Quality assurance plan
- Delegation of authority (if appropriate)
- Individual quality control plans (IQCP) if applicable
- Safety policies
- Evidence of personnel qualifications, training, and experience
- Evidence of competency assessment (using the six modes of competency assessment)

**For the past two years, the following documents should be available:**

- Patient test orders or requisitions
- Accession logs
- Test results logs or worksheets
- Instrument printouts or tapes
- Records of quality control, calibration, calibration verification (if applicable), equipment function checks, maintenance activities, temperature checks, humidity monitoring, etc.

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## Records Needed, (cont'd from page 3)

- Documentation of quality assurance activities, problem resolution, corrective actions (when applicable)
- Proficiency testing results and all pertinent documentation for proficiency testing such as signed attestation statements, instrument printouts, final reports, etc.
- Patient test reports or charted results

During the survey, the surveyor will point out any concerns or deficiencies as they are found, and will give the staff or management an opportunity to clarify any misunderstandings or provide records as required. If records are not available or incomplete, the laboratory will be cited for record retention.

# Proficiency Test Result Scored 80 Percent - Now What?

by Susan Walker, Department of Health/LQA

Although 80 percent is considered passing in all specialties except for some of the blood bank tests, there should be some sort of evaluation of the test that failed to meet acceptable limits. Keep in mind that you would not accept one out of five patients' samples to be reported incorrectly; therefore, you should not accept one out of five proficiency test results.

**What shall I do?** These are some of the areas you can investigate:

- Review the documentation on the day of testing and check the quality control results for that test.
- Were the quality control results acceptable? If so, look at calibration.
- Is the calibration current? If so, look at peer review quality control results.
- Are the peer review quality control results acceptable? If so, look at the maintenance records.
- Has maintenance on the instrument been performed regularly? If so, look at the storage requirements for the proficiency testing samples and reagents. If these are acceptable, you can look at the testing personnel.
- Are the testing personnel competent to perform this test and are they following the PT company's procedure for performance?

**Clerical Errors:** Remember that many times the failure is because of a clerical error, so check that and figure out a way to avoid this type of error.

The laboratory manager can most likely define more items to be verified before a conclusion can be determined. Record all of this investigation and document any corrective action as appropriate. Be sure that the laboratory director is aware of any proficiency test failures as the laboratory director is ultimately responsible for all patient testing.

## Approved PT Providers

[Amer. Acad. of Family Physicians](#) (800) 274-7911

[Amer. Assoc. of Bioanalysts](#) (800) 234-5315

[American Proficiency Institute](#) (800) 333-0958

[ACP Medical Lab Evaluation](#) (800) 338-2746

[College of American Pathologists/EXCEL](#)  
(800) 323-4040

[WSLH](#) (800) 462-5261

For answers to your PT questions, go to the [LQA website](#) or call Nora Estes at (253) 395-6747.

## Calendar of Events

### Training Classes:

#### [2019 ASCLS-WA Spring Meeting](#)

April 25-26 Olympia

#### [2019 Northwest Medical Laboratory Symposium](#)

October 9-12 Lynnwood

#### [26th Annual Clinical Laboratory Conference](#)

November 2019 Tukwila

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.



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For persons with disabilities, this document is available upon request in other formats. To submit a request, please call 1-800-525-0127 (TTY/TDD 1-800-833-6388).